APIC
ASSOCIATION FOR PROFESSIONALS IN
INFECTION CONTROL AND EPIDEMIOLOGY, INC.

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October 29, 1999

Dockets Management Branch
(HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 106 1
Rockville, MD 20852

Dear Sir or Madam:

On behalf of the Association for Professionals in Infection Control and Epidemiology (APIC), I thank you for this opportunity to offer comment on the agency's proposed rule for the reclassification of surgeon's and patient examination gloves. This is an important issue and we look forward to working with the FDA, as the agency considers regulation in this area.

The Association for Professionals in Infection Control and Epidemiology (APIC) is a nonprofit professional organization representing some 12,000 members. APIC's membership is comprised of nurses, medical technologists, microbiologists, epidemiologists, physicians and other health care personnel whose primary responsibility within their facilities is infection prevention and control. APIC has long been both a patient and employee advocate throughout its 27-year history. Our emphasis is on surveillance, prevention and control of nosocomial infections, science-based practice, policy and procedures, and outcome monitoring and performance measurement.

APIC has significant concerns that the proposed rule is going to increase costs to health care facilities considerably. One particularly troubling aspect of the proposed rule appears on page 4 17 15. As currently worded, FDA proposes "to require expiration dating on the labeling of all powdered surgeon's and patient examination gloves and powder free surgeon's and patient examination gloves."

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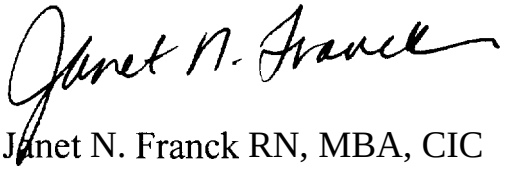
The text continues, “Expiration dates for sterile surgeon’s or patient examination gloves should either be based on the shelf-life determined by stability studies as outlined in the proposed rule, or on the sterility shelf-life, whichever is shorter.”

This may be problematic, since many hospitals have converted to Event-Related Sterility (i.e., the sterile packaged material is sterile until the package is damaged or opened). If the FDA requires manufacturers to place a sterility-related expiration date on sterile gloves, this will force those hospitals practicing event-related sterility to practice two standards of care. The gloves (including exam gloves) will carry expiration dates while hospital sterilized goods will not. Although gloves may expire because the material they are made of has degraded, the expiration should not be based on some artificial notion of sterility. We hope the agency will consider this crucial point.

Thank you for your consideration of APIC’s concerns. We appreciate the FDA’s efforts to ensure the safety of patients and look forward to working with you in the future. If you have questions or need additional information, please contact Jennifer Thomas, Director of Government and Public Affairs, at 202-789- 1890 or <jthomas@apic.org>.

Sincerely,



Janet N. Franck RN, MBA, CIC
1999 APIC President

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